

We claim:

1. An assay device comprising:

a planar base comprising a major planar wall and a side wall transverse to the
5 major planar wall, the side wall surrounding the major planar wall to define a cavity with
an open face opposite the major planar wall; and

an insert for being received in the cavity, the insert comprising:

first and second opposed surfaces, the first surface comprising a planar portion
opposing the major planar wall when the insert is received in the cavity, the planar
10 portion and the major planar wall being separated by a distance to define a space and the
first surface of the insert and the major planar wall defining an entrance to the space, the
distance between the planar portion and the major planar wall being effective to cause
capillary flow of a fluid sample at the entrance, into the space;

the second surface of the insert defining:

15 an input portion for receipt of the fluid sample, the input portion being in fluid
communication with the entrance to the space, and

a reading portion for analyzing the fluid sample drawn into the space, the reading
portion opposing the planar portion of the insert.

2. The assay device of claim 1, wherein the input portion defines at least one

20 passage through the insert to the entrance.

3. The assay device of claim 2, further comprising a filter proximate the
input portion.

4. The assay device of claim 3, wherein the filter is within the passage.

5. The assay device of claim 4, wherein the filter comprises a dynamic capillary filter.

6. The assay device of claim 5, wherein the dynamic capillary filter comprises a plurality of particles, the particles being transiently abutting when a fluid passes through the particles, the transiently abutting particles defining transient interstitial spaces therebetween.

7. The assay device of claim 6, wherein the particles are microspheres.

8. The assay device of claim 6, further comprising a porous membrane supporting the plurality of particles in the passage, the porous membrane having a pore size less than the size of the particles.

9. The assay device of claim 8, wherein:

the passage extends from the second surface of the insert to the first surface of the insert, the passage having an entrance at the second surface and an exit at the first surface; and

15 the porous membrane is connected to the second surface, covering the exit of the passage, to prevent passage of the particles out of the passage, through the exit.

10. The assay device of claim 9, wherein the exit of the passage is in the major planar portion.

11. The assay device of claim 9, wherein the passage is tapered inward from 20 the exterior surface towards the interior surface.

12. The assay device of claim 1, wherein, when the insert is within the chamber, the space has a defined volume.

13. The assay device of claim 2, wherein the input portion comprises a least one surface tapered towards the passage.

14. The assay device of claim 1, wherein the major planar wall is transparent.

15. The assay device of claim 1, wherein at least a portion of the insert 5 including the planar portion of the first surface is transparent.

16. The assay device of claim 1, wherein the second surface of the insert has a portion opposed to the input portion and distanced a sufficient distance from the planar bottom wall so that less capillary force is generated between the portion and the bottom wall than the capillary force generated in the space.

10 17. The assay device of claim 2, wherein the input portion comprises an upstanding wall having at least a portion adjacent to the passage.

18. The assay device of claim 17, wherein the upstanding wall circumscribes the input portion.

19. The assay device of claim 1, further comprising a lid slidably coupled to 15 the planar base, for selectively covering the input portion.

20. The assay device of claim 1, wherein the insert and the base are transparent.

21. The assay device of claim 1, wherein the side wall is perpendicular to the base.

20 22. The assay device of claim 1, further comprising a reagent within the space.

23. The assay device of claim 1, wherein the insert is press-fit in the chamber.

24. The assay device of claim 1, further comprising a pair of opposing reflective surfaces, on opposite sides of the space.

25. The assay device of claim 24, wherein the first reflective surface is on the planar portion and the second reflective surface is on the planar bottom wall.

5 26. The assay device of claim 24, wherein one of the reflective surfaces defines an inlet for radiation into the space and the other reflective surface defines an outlet for radiation out of the space, the inlet and the outlet being positioned with respect to each other such that radiation entering the space through the inlet is reflected multiple times between the reflective surfaces prior to exiting the space.

10 27. The assay device of claim 1, further comprising a gel in the space.

28. The assay device of claim 27, further comprising reagents in the gel.

29. The assay device of claim 1, further comprising a dry matrix material in the space.

15 30. The assay device of claim 29, further comprising reagents in the dry matrix.

31. The assay device of claim 1, wherein the cavity is recessed in the base.

32. The assay device of claim 1, wherein the side wall extends from the base.

33. The assay device of claim 1, wherein the side wall comprises a plurality of walls.

20 34. The assay device of claim 1, wherein the planar portion of the first surface of the insert comprises legs for supporting the insert in the cavity.

35. The assay device of claim 1, wherein the major planar wall comprises legs for supporting the insert in the cavity.

36. An assay device comprising:
a base comprising a major wall and at least one side wall transverse to the major
5 wall, the side wall and the major wall defining a cavity; and

an insert received in the cavity, the insert comprising:
first and second opposed surfaces, the first surface comprising a portion opposing
the major wall, the portion of the first surface and the major wall being separated to
define a space and the first surface of the insert and the major wall defining an entrance
10 to the space;

the second surface of the insert defining an input portion for receipt of a fluid
sample, the input portion comprising:

a passage defined by the insert, the passage extending through the insert, the
passage having an entrance in the input portion and an exit in the first surface, the exit
15 being proximate to the entrance to the space;

a plurality of particles supported within the passage, wherein, when a fluid sample
passes through the passage, the particles are transiently abutting, defining transient
interstitial spaces therebetween, to filter materials greater than a predetermined size from
the fluid sample; and

20 the second surface of the insert further defining a reading portion for analyzing
the sample drawn into the space.

37. The assay device of claim 36, further comprising a porous material attached to the first surface of the insert, over the exit, to support the particles.

38. The assay device of claim 37, wherein the porous membrane is chosen from the group consisting of a nylon mesh, a polyester mesh, a polycarbonate film and a
5 polysulfone membrane.

39. The device of claim 36, further comprising a reagent associated with the particles.

40. The assay device of claim 38, wherein the reagent comprises a label specific to an analyte.

10 41. The assay device of claim 40, wherein the label is a fluorescent label, a radioactive label or a metal label.

42. The assay device of claim 36, further comprising a plurality of second particles having a size less than the size of the plurality of first particles.

15 43. The assay device of claim 42, further comprising a reagent associated with the second particles.

44. The assay device of claim 36, further comprising a reagent in the space.

45. The assay device of claim 36, wherein the particles are chosen from the group consisting of latex, glass, silicon and sand.

46. The assay device of claim 36, wherein the cavity is recessed in the base.

20 47. The assay device of claim 36, wherein the side wall extends from the base.

48. The assay device of claim 36, wherein the distance between the portion and the major wall is effective to cause capillary flow of a fluid sample at the entrance into the space.

49. An assay device comprising:

5 a base defining an enclosed cavity, the cavity having a major surface and an open face opposite the major surface; and

a plate within the cavity, the plate having a first surface and a second surface opposed to the first surface, the second surface opposing the major surface;

10 wherein a portion of the second surface is separated from the major surface to define a space, and the insert and the major surface of the cavity define an entrance to the space; and

the first surface of the plate defines an input portion for the receipt of a fluid sample, and

a reading portion for viewing fluid sample drawn into the space.

15 50. The assay device of claim 49, wherein the cavity is recessed in the base.

51. The assay device of claim 49, further comprising a side wall extending transverse to the base and surrounding the major surface, defining the cavity.

52. The assay device of claim 49, wherein the insert defines at least one passage from the input portion to the entrance to the space.

20 53. The assay device of claim 49, further comprising a plurality of particles in the at least one passage, the particles being transiently abutting when a fluid passes through the particles, the transiently abutting particles defining transient interstitial

spaces therebetween, the particles removing materials greater than a predetermined size from the fluid sample.

54. The assay device of claim 49, further comprising a reagent in the space.

55. The assay device of claim 49, wherein the portion of the second surface and the major surface are separated by a distance such that fluid proximate the entrance is drawn into the space by capillary force.

56. An assay device comprising:

a base comprising a major wall and a side wall transverse to the major wall, the side wall and major wall defining a cavity; and

10 an insert press-fit in the cavity, the insert comprising:

first and second opposed surfaces, the second surface comprising a portion opposing the major wall, the portion of the second surface and the major wall having a space therebetween;

15 the first surface of the insert defining an input portion for receipt of a fluid sample, the input portion being in fluid communication with the space; and
a reading portion for analyzing fluid sample drawn into the space.

57. The assay device of claim 56, wherein the side wall has an interior surface comprising a plurality of protrusions engaging a side edge of the insert in the press-fit.

20 58. The assay device of claim 57, further comprising a plurality of second protrusions from the side edge of the insert, the locations of the plurality of second protrusions corresponding to the locations of the plurality of first protrusions on the side

wall, so that the first protrusions bear against the second protrusions when the insert is press-fit within the chamber.

59. The assay device of claim 56, wherein the insert has a side edge comprising a plurality of protrusions engaging an interior surface of the side wall.

60. The assay device of claim 56, further comprising a plurality of second protrusions protruding from the interior surface of the side wall, the locations of the plurality of second protrusions corresponding to the locations of the plurality of first protrusions on the side wall, so that the first protrusions bear against the second protrusions when the insert is press-fit within the chamber.

10 61. The assay device of claim 56, further comprising a reagent within the space.

62. The assay device of claim 56, wherein the side wall extends transverse to the base and surrounds the major wall, defining the cavity.

15 63. The assay device of claim 56, wherein the insert defines at least one passage through the insert, providing fluid communication from the input portion to the space.

20 64. The assay device of claim 63, further comprising a plurality of particles in the at least one passage, the particles being transiently abutting when a fluid passes through the particles, the transiently abutting particles defining transient interstitial spaces therebetween, the particles removing materials greater than a predetermined size from the fluid sample.

65. The assay device of claim 56, wherein the portion of the surface and the major wall are separated by a distance effective to cause capillary flow of a fluid sample into the space.

66. An assay device comprising:

5 a base defining an enclosed cavity, the cavity having a major surface and an open face opposite the major surface; and

a plate within the cavity, the plate having a first surface and a second surface, the first surface opposing the major surface;

wherein a portion of the first surface is separated from the major surface to define 10 a space, and the insert and the surface of the cavity define an entrance to the space;

the first surface of the plate defining an input portion for the receipt of a fluid sample; and

a reading portion for analyzing fluid sample drawn into the space;

the assay device further comprising a lid slideably engaging the base, such that 15 the lid may be selectively positioned over the input portion.

67. The assay device of claim 66, wherein the base defines a pair of grooves for engaging the lid.

68. The assay device of claim 67, wherein the lid comprises:

20 a major portion for selectively covering the input portion, the major portion having two opposing ends;

two arm portions, each having a first end depending from a respective opposing end of the major portion, and a second end; and

inwardly directed flanges depending from the second end of each arm, each flange engaging a respective groove.

5 69. The assay device of claim 68, wherein the side wall has a top edge, and at least one protrusion protruding from the top edge of the side wall adjacent to the input portion, such that when the lid is moved over the protrusion, the lid is locked in place.

70. The assay device of claim 66, wherein the lid may be selectively positioned over the reading portion.

71. An assay device comprising:

10 a base defining an enclosed cavity, the cavity having a major surface and an open face opposite the major surface; and

a plate within the cavity, the plate having a first surface and a second surface, the first surface opposing the major surface;

15 wherein a portion of the first surface is separated from the major surface to define a space, and the first surface and the surface of the cavity define an entrance to the space;

the first surface of the plate defining an input portion for the receipt of a fluid sample, the insert defining at least one passage through the insert, providing fluid communication from the input portion to the entrance to the space;

the input portion further comprising a wall extending transverse to the input portion, the wall surrounding the input portion, and

20 the second surface of the plate further defining a reading portion for analyzing fluid sample drawn into the space.

72. The assay device of claim 71, wherein the input portion comprises at least one surface tapered towards the passage.

73. The assay device of claim 72, wherein the input portion comprises three surfaces tapered towards the passage.

5 74. The assay device of claim 71, comprising two adjacent passages.

75. The assay device of claim 71, wherein a portion of the wall is adjacent to the passage.

76. The assay device of claim 71, wherein the cavity is recessed in the base.

77. The assay device of claim 71, further comprising a side wall extending 10 transverse to the base and surrounding the major surface, defining the cavity.

78. The assay device of claim 71, further comprising a plurality of particles in the at least one passage, the particles being transiently abutting when a fluid sample passes through the particles, the transiently abutting particles defining transient interstitial spaces therebetween, the particles removing material greater than a predetermined size 15 from the fluid sample.

79. The assay device of claim 71, further comprising a reagent in the space.

80. The assay device of claim 71, wherein the portion of the first surface is separated from the major surface by a distance effective to cause capillary flow of fluid sample at the entrance, into the space.

20 81. An assay device comprising:

a base comprising a major wall and a side wall transverse to the major wall, the side wall surrounding the major wall to define a cavity with an open face opposite the major wall; and

an insert for being received in the cavity, the insert comprising:

5 first and second opposed surfaces, the first surface comprising a portion opposing the major wall when the insert is received in the cavity, the portion and the major wall being separated to define a space and the first surface of the insert and the major wall defining an entrance to the space;

the second surface of the insert defining:

10 an input portion for receipt of the fluid sample, the input portion being in fluid communication with the entrance to the space, and

 a reading portion for analyzing a fluid sample in the space, the reading portion opposing the space.

82. The assay device of claim 81, further comprising a multi-layer carrier in
15 the space.

83. The assay device of claim 82, wherein the multi-layer carrier comprises a dry matrix layer and a gel layer adjacent to the dry matrix layer.

84. The assay device of claim 83, wherein at least one of the two layers
comprises a reagent.

20 85. The assay device of claim 83, wherein each layer comprises a different
reagent.

86. The assay device of claim 82, comprising alternating dry matrix layers and gel layers.
87. The assay device of claim 83, wherein the dry matrix layer comprises cellulose.
- 5 88. The assay device of claim 81, further comprising a layer of gel in the space.
89. The assay device of claim 87, wherein the gel layer comprises agar.
90. An assay device comprising:
 - a base defining an enclosed cavity, the cavity having a major surface and an open face opposite the major surface;
 - a plate within the cavity, the plate having a first surface and a second surface opposed to the first surface, the first surface opposing the major surface of the cavity;
 - 10 wherein a portion of the first surface is separated from the major surface to define a space, and the insert and the major surface of the cavity define an entrance to the space;
 - 15 and
 - the second surface of the plate defines an input portion for the receipt of a fluid sample, and
 - a second portion opposing the space; and
 - the assay device further comprising a pair of opposing reflective surfaces, on
 - 20 opposite sides of the space.

91. The assay device of claim 90, wherein the first reflective surface is on the first surface of the plate and the second reflective surface is on the major surface of the cavity.

92. The assay device of claim 91, wherein one of the reflective surfaces defines an inlet for radiation into the space and the other reflective surface defines an outlet for radiation out of the space, the inlet and the outlet being positioned with respect to each other such that radiation entering the space through the inlet is reflected multiple times between the reflective surfaces prior to exiting the space.

93. The assay device of claim 91, wherein the first reflective surface is on the second portion of the second surface and the second reflective surface is on an underside of the base.

94. The assay device of claim 56, further comprising protrusions on the portion of the first surface opposing the major wall, the protrusions engaging the major wall.

95. The assay device of claim 94, wherein the protrusions extend longitudinally extending across the portion.

96. The assay device of claim 56, further comprising protrusions on the major wall, the protrusions engaging the portion of the first surface.

97. The assay device of claim 96, wherein the protrusions extend longitudinally across the major wall.

98. The assay device of claim 56, further comprising means for supporting the portion of the first surface opposing the major wall, a predetermined distance from the major wall, said means being between the portion and the major wall.